

**AMENDMENT TO
BROAD AGENCY ANNOUNCEMENT FOR THE ADVANCED RESEARCH AND
DEVELOPMENT OF CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR (CBRN)
MEDICAL COUNTERMEASURES FOR
BARDA**

Broad Agency Announcement Number: BAA-16-100-SOL-00001
Amendment Number: 0004

A. SUMMARY OF CHANGES

This amendment issues a new subsection to the section entitled Area of Interest #6:
Clinical Diagnostics.

B. AMENDMENTS TO BAA

- (1) The section entitled Area of Interest #6: Clinical Diagnostics entitled Research Areas of Interest is changed by adding the following new subsection entitled 6.9.3 Blood screening assays:

6.9.3 Blood screening assays: Development, system integration and validation of rapid, highly sensitive, accurate high-throughput molecular assays for the detection of Zika virus in donated blood and blood components. BARDA will support preparation for US regulatory submissions including, at a minimum, validation studies necessary to produce sufficient data to support an Investigational New Drug (IND) submission. The assays shall be designed and developed for rapid integration into instrument systems (high-throughput platforms) already used for blood donor screening in the United States or next generation instruments for these systems. Donor screening assays for the detection of Zika virus in more advanced stages of development that may be more quickly considered for IND use or FDA approval will be given priority. Assays should be at a maturity level equal to or greater than TRL-5.

[End of Amendment No. 0004]